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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,503

02/06/2006

Ryouichi Hoshino

2006-0019A

7559

513 7590 01/22/2008

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2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

4173

MAIL DATE

DELIVERY MODE

01/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,503	<b>Applicant(s)</b> HOSHINO ET AL.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/31/2006</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1 – 5 are pending and are examined on the merits.

### ***Specification***

1. The disclosure is objected to because of the following informalities: a presumed typographical error and poor grammar are present. For example, lines 20 - 23 of p 4 of the specification states "a material that swells as it absorbs a solvent, so that the colloid particles are cross-linked [sic] between polymers another to form a three-dimensional network structure". This may be in part due to the translation of the specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohyama et al. (EP 1245232 A1, published October 2, 2002).

Examples 1 – 9 contain solid tablets of KRP-197, also known as 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide (paragraph [0001]), with hydroxypropylmethylcellulose. Hydroxypropylmethylcellulose is exemplified in claim 2 of the instant application as a gel-forming material. A small amount of KRP-127 and carriers are granulated and pressed into tablets (paragraph [0004]). The tablet is made by mixing the excipients and binders such as hydroxypropylmethylcellulose followed by granulation (paragraph [0006]). The granulation can be a wet, fluidized bed or dry process (paragraph [0006]).

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

**MPEP 2113.**

The compositions disclosed in Ohyama et al. encompass the same ingredients as those claimed by applicant and thus the disclosure of Ohyama et al. anticipates the claims of the instant application.

### ***Claim Rejections - 35 USC § 103***

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 – 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al.

Ohyama et al. discloses an oral solid pharmaceutical comprising 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide and ingredients such as

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hydroxypropylmethylcellulose (p 2, ln 39). Ohyama does not disclose tablets in which 18 – 73 weight percent is hydroxypropylcellulose. Example 5, paragraph [0015] contains 4.8% hydroxypropylmethylcellulose by weight.

Ohyama et al. also discloses other ingredients such as methylcellulose (p 2, ln 39), polyvinyl alcohol (p 2, ln 40) and polyvinyl pyrrolidone (p 2, ln 40) that may be present in the pharmaceutical compositions with the KRP-197. These ingredients are exemplified by Applicant on p 5 of the instant application as gel-forming materials.

As to the amount of hydroxypropylmethylcellulose present in the tablet, it would be a matter of routine experimentation to one ordinary skill in the art to adjust the amount of this material present. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

#### **MPEP 2144.05.**

Therefore, it would have been obvious to one of ordinary skill in the art to construct a tablet comprising KRP-197 and a gel-forming material such as the claims of the instant application given the teachings of Ohyama et al as to a tablet composition comprising KRP-197 and gel-forming materials such as methylcellulose, polyvinyl alcohol and polyvinyl pyrrolidone.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/795,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application recite a sustained-release tablet comprising a gel-forming material and 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide. This compound is also known as imidafenacin (p 7, In 16 – 18 of co-pending Application ‘792). As described in the co-pending application, a “multiple-unit oral sustained release preparation” uses granules or powders as the constituting unit (p 7, In 23 – 25 and line 2 of claim 13). A tablet made by compacting the granules would therefore be a multiple-unit oral sustained release preparation. As described in the instant application, the presence of a gel-forming material results in tablets that are capable of sustained release of the active ingredient. These tablets can

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be made compressing granulation, or a multiple-unit sustained release preparation of 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide as described in claim 13 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Claims 1 – 5 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M Westerberg whose telephone number is 571-270-3532. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.



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/NMW/

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 4173